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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/549,385	Confirmation No.: 6082
Applicant	:	Thorsten Siess, et al.	
Filed	:	June 30, 2006	
Art Unit	:	3763	
Title:	:	INTRODUCTION DEVICE FOR INTRODUCING AN OBJECT INTO A VESSEL OF A BODY	
Examiner	:	Quynh-Nhu Hoang Vu	
Docket No.:	:	IMPEL.71975	
Customer No.	:	24201	July 31, 2009

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents

REPLY BRIEF

This Reply Brief is responsive to the Examiner's Answer mailed June 25, 2009 in the appeal from the Final Office Action of May 14, 2008. This Reply Brief is being filed within the term provided by and in compliance with 37 CFR 41.41.

ARGUMENT

The Examiner continues to insist that the plastic covered metal coil of the primary reference in fact teaches a thin sheath **in combination** with a retractable dilator. Such mischaracterization not only defeats the very intent and purpose of the introducer device as is articulated in the reference but also requires a reversal of the ostensibly irreversible processes by which the plastic covering is joined to the metal coil to positively prevent the retraction of the metal coil from its plastic covering.

The primary reference provides for a **non-kinking** introducer sheath and **teaches** that the wall thickness of the relatively thick plastic tubing that is commonly used as an introducer can substantially be reduced when combined with a metal coil to thereby allow for a reduction of the overall diameter of the introducer yet retain its non-kinking property and thereby prevent the sheath from collapsing. By removing the metal coil and characterizing its thin plastic covering as the actual introducer sheath rather than merely a covering of the sheath, the device would be free to collapse and thereby defeat the stated purpose for the substitution of the metal coil for a portion of the plastic tubing in the first place. This clearly flies in the face of the **teaching** of the cited reference.

The processes that are described in the reference by which the metal coil is to be combined with the plastic layer positively prevent the retraction of the metal coil. In addition to teaching the heat shrinking of plastic tubing onto the metal coil, molding, over-extruding or dip coating the coil are described as viable alternatives to ensure that the plastic projects into the space between adjacent coils to prevent "**unwanted longitudinal displacement** of one turn relative to another." There could be no more definitive statement that the coil is intended not to be retractable from the plastic covering or coating. Despite the fact that removal of the metal coil

from within its plastic covering would defeat the stated purpose for its disposition within the plastic covering and despite the fact that the reference very clearly provides for a positive joining of the two components, the Examiner insists that the reference **teaches** the combination of a thin channel with a **retractable** dilator.

The Examiner further tries to rely on the applicants' admission that a channel made of hard plastic is conventional. However, the Examiner conveniently neglects to include the rest of the applicants' "admission", namely that it is conventional for such channel to be "**thick-walled**." The teaching of plastic sheaths that are sufficiently thick to prevent collapse or kinking in combination with the teaching of the primary reference to instead rely on a plastic covered metal coil in order to prevent collapse or kinking does not in any way suggest a thin-walled sheath that is readily collapsible. As such, both the "admission" as well as the primary reference teach directly away from an introducer device that relies on a plastic channel with a wall thickness no larger than a mere 0.06 mm.

The Examiner goes on to assert that the metal coil of the primary reference can in fact be characterized as a "dilator" because, in essence, it serves to dilate. While the described device may be capable of maintaining tissue in a dilated configuration, the reference teaches that a dilator is to be used to dilate the tissue in the first place (page 4, line 53). Notwithstanding this distinction, the problem with the Examiner's position arises in view of the fact that the cited reference unequivocally teaches that the dilator is not to be retractable from the sheath. As a consequence, for a given inner diameter, the outer diameter of such introducer is necessarily greater than the diameter of an introducer sans a dilator and would thereby inflict greater trauma on the surrounding tissue.

The Examiner then challenges the effect of the term "adapted for retraction," stating that such terminology does not constitute a limitation in any patentable

sense and cites *In re Hutchinson*, 69 USPQ 138. A closer reading of the citation however reveals that the reason the use of the term was found to be non-limiting in that particular case was because of its use in the claim's **introductory clause**. In contrast thereto, the term is used in claims of the present invention with regard to one of the claimed elements and while the Examiner states that the "adapted for retraction" term merely requires the ability to so perform, the metal coil in the cited reference most definitely does NOT have the ability to so perform. The Examiner does point out that the metal coil in the cited reference is retractable from the sheath BEFORE it is fully assembled in the manner taught by the reference (i.e. heat shrunk, molded, over-extruded or dip coated). This however ignores the **teaching** of the reference to positively join the plastic covering to the metal coil and is analogous to the argument that the pages of a book are "adapted for removal" from its cover because the pages were loose before the book was bound.

The Examiner further asserts that the applicants fail to recite in the claims the features upon which the applicants rely to distinguish the cited in the reference, presumably referring to the "deformability" of the claimed channel and the "non-kinking" nature of the introducer of the primary reference. As had previously been argued, in order to avoid confusion (and functional language rejections) as to the import of such terms in a patentable sense, the device was instead claimed purely in terms of its structure, i.e. exclusively formed of plastic with a wall thickness not larger than 0.06 mm. These limitations serve to very effectively distinguish the cited art.

Finally, the Examiner argues that it is reasonable to combine the two cited references because the two references disclose all of the elements (as interpreted by the Examiner) that are claimed. This of course completely avoids the issue of a teaching or suggestion to do so. Moreover, both references teach the exact same

solution to the problem, namely the conventional, to the extent that both provide for an essentially non-kinking, non-collapsing introducer sheath. The secondary reference achieves this with the use of a relatively thick plastic sheath, while the primary reference achieves this with the use of a thinner plastic sheath that is fused to a metal coil. Both references teach away from the concept of a thin, readily collapsible sheath, in combination with a **retractable** dilator.

CONCLUSION

For the foregoing reasons, it is maintained that the present invention as claimed is not rendered obvious by the cited art. Accordingly, appellants respectfully request reversal of the rejection of all claims.

The commissioner is authorized to charge any deficiencies in fees or credit any overpayments to our Deposit Account No. 06-2425.

Respectfully submitted,

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